UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Chemical: Difenoconazole
PC Code: 128847
DP Barcodes: D351238 (GA), D351716 (CA)

MEMORANDUM

SUBJECT: Environmental Fate and Effects Division Risk Assessment for the Section 18 Emergency Exemption of Difenoconazole in GA and CA

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Please find the attached Environmental Fate and Effects Division's (EFED) environmental risk assessment for the proposed Section 18 Emergency Exemption for use of Inspire Super™ MP on cucurbits (watermelons, cantaloupes and cucumbers) in Georgia during the 2008 use season for control of gummy stem blight. The maximum proposed single application rate is 0.114 lb a.i./A with 4 applications for an annual maximum rate of 0.46 lb a.i./A. The Inspire Super™ MP multipack, consisting of Inspire Super™ MP fungicide and Vangard® WG fungicide, from Syngenta Crop Protection contains the active ingredients difenoconazole and cyprodinil. This assessment only pertains to risk due to difenoconazole.

In addition, there is a proposed Section 18 use on almonds in California limited to Butte, Glenn, Kern and Tehama Counties for control of alternia leaf spot. The request is for use of Inspire (0.11 lb a.i./A) with two applications per year and alternated with Endorse® (0.11 lb a.i./A, active ingredient is polyoxin D). The two products are to be applied

separately and not tank mixed.

Estimated Drinking Water Concentrations

Among all the registered uses for difenconazole, the highest estimated drinking water concentrations (EDWCs) from surface water sources were derived for aerial applications of difenoconazole to California ornamental nurseries at the maximum annual application rate of 0.60 kg ai/ha. The second highest EDWC were derived for Maine potatoes at the maximum annual application rate of 0.48 kg ai/ha. These concentrations are recommended to be used for the human health risk assessment purpose. For detail information regarding drinking water assessment refer to document untitled, Amended Difenoconazole (Parent Only) Drinking Water Assessment in Support of New Use Registration Action for Fruiting Vegetables, Tuberous, Corn, Vegetables Subgroup, Pome Fruit, Ornamentals, and Sugar beets, from June 19, 2007 (D333319 and D340041).

For same difenconazole registered uses on nurseries and potato, the SCI-GROW model estimated the concentration of difenoconazole in drinking water from shallow ground water sources to be 1.08×10^{-2} µg/L for agricultural uses (nurseries), and 1.28×10^{-2} µg/L for non-agricultural uses (potato). These concentrations can be considered as both the acute and chronic values.

In clear natural water, difenoconazole may break down by photolysis to triazolyl acetic acid and further to triazole methanol and triazole. 1,2,4-Triazole and its conjugates (triazole alanine and triazole acetic acid) are common metabolites to the class of compounds known as the triazole-derivative fungicides (T-D fungicides, conazoles). A separate cumulative risk assessment was conducted on 1,2,4-trizole degradates. The Office of Pesticide Program's Health Effects Division (HED) has conducted aggregate human health risk assessments for 1,2,4-triazole and triazole conjugates which was completed on Feb 7, 2006 (D320683). A Tier II drinking water assessment for 1,2,4-triazole was completed in Feb 28, 2006 (D320682).

Ecological Assessment

Based on available screening-level information, the greatest concerns for ecological risks based on direct effects lie with chronic risk to aquatic invertebrates, birds, mammals and unknown risk to terrestrial plants. A qualitative study was submitted for terrestrial plants and while no toxic effects were observed, risk cannot be precluded at this time. Therefore, these species and the species that they represent as surrogates were identified as being of potential concern for direct and indirect effects to listed and non-listed species. A summary of the potential for direct and indirect effects to listed species, summarized by taxonomic group, is provided in **Table 1**.

Chronic LOCs are slightly exceeded for freshwater invertebrates for the Florida cucumber and Georgia onion scenarios which represents application to cucumbers, cantaloupes, and watermelons in Georgia (RQ = 1.02 (ground) - 1.08 (aerial)) based on four applications. However, based on the proposed label language for Inspire Super MP, it is recommended for resistence management that Inspire Super MP be used in the

blocking program using the maximum of two consecutive applications before rotating to fungicides with another mode of action registered for those uses. For the aquatic assessment, four consecutive difenoconazole applications were modeled. The current version of PRZM-EXAM does not allow modeling alternated applications as recommended by registrant in the proposed label. Therefore, the modeling of cucurbits may be conservative with regard to the application regime. At two consecutive applications, there is no potential chronic risk to freshwater invertebrates.

Chronic LOCs are also exceeded for estuarine/marine crustaceans for both of the proposed crops with RQs almost two orders of magnitude greater than the LOC (1.0). The RQs are based on the mysid life cycle toxicity test which resulted in a reproduction nondefinitive NOAEC <0.115 µg ai/L based on number offspring/female/ reproduction day. There were significant adverse effects on reproductive success at all treatment levels compared to the negative control (42-68%). The NOAEC value for growth based on male dry weight was 0.311 µg ai/L. When RQs are calculated based on the NOAEC for growth, LOCs are also exceeded for all proposed crops. Therefore, there is a potential direct risk for estuarine/marine crustaceans exposed to difenoconazole residues in the proposed use areas of cucurbits in Georgia and almonds in California that are coastal areas.

Mammalian dose-based chronic LOCs were exceeded for all food groups except seeds (RQs = 1.07 – 30.15) based on two and four consecutive applications. Mammalian dietary-based chronic LOCs were exceeded for all food groups except fruits, pods, seeds, and large insects (RQs = 1.11 – 3.59) based on two and four consecutive applications.

There is no dose-base risk to birds; however, dietary-based chronic LOCs were exceeded for all food groups except fruits, pods, seeds, and large insects for both of the proposed crops. At two consecutive applications RQs range from 1.03 – 2.25. At four consecutive applications, RQs range from 1.88 to 4.10. Based on this analysis, listed and non-listed birds that feed on grasses and broadleaf plants may be at risk of experiencing chronic and reproductive effects if exposed to difenoconazole.

Table 1. Listed Species Risks Associated With Direct or Indirect Effects Due to Applications of Difenoconazole.		
Listed Taxonomy	**Direct Effects**	**Indirect Effects**
Terrestrial and semi-aquatic plants – monocots	Unknown [g]	Yes [f]
Terrestrial and semi-aquatic plants – dicots	Unknown [g]	Yes [f]
Terrestrial invertebrates	No	Unknown [g]
Birds	Chronic	Yes [c, d, e]
Terrestrial phase amphibians	Chronic [b]	Yes [c, d, e]
Reptiles	Chronic [b]	Yes [c, d, e]
Mammals	Chronic	Yes [c, d, e]
Aquatic vascular plants	No	No
Aquatic non-vascular plants [a]	No	No
Freshwater fish	No	Yes [e]
Aquatic phase amphibians	No	Yes [e]
Freshwater crustaceans	Chronic (GA curcurbits only at 4 consecutive applications)	Yes [e]
Estuarine/marine Mollusks	No	No
Estuarine/marine crustaceans	Chronic	No
Estuarine/marine fish	No	Yes [e]

[a] At the present time no aquatic non-vascular plants are included in Federal listings of threatened and endangered species. The taxonomic group is included here for the purposes of evaluating potential contributions to indirect effects to other taxonomy and as a record of exceedances should future listings of non-vascular aquatic plants warrant additional evaluation of Federal actions.

[b] Terrestrial phase amphibians and reptiles estimated using birds as surrogates. Aquatic amphibians estimated using freshwater fish as surrogates.

[c] Chronic LOC exceeded for some feeding guilds and size classes of birds.

[d] Chronic LOC exceeded for some feeding guilds and size classes of mammals.

[e] Potential Risk to freshwater and estuarine/marine crustaceans.

[f] Indirect effects may be caused by plants that rely on affected mammals, birds, amphibians, and reptiles as pollinators.

[g] Risk cannot be precluded because the terrestrial plant toxicity test was qualitative.

Key Uncertainties and Information Gaps

The following uncertainties and information gaps were identified:

- Difenoconazole may break down to form triazolyl acetic acid and further to triazole methanol and triazole. 1,2,4-Triazole and its conjugates (triazole alanine and triazole acetic acid) are common metabolites to the class of compounds known as the triazole-derivative fungicides (T-D fungicides, conazoles). A separate cumulative risk assessment was conducted on 1,2,4-trizole degradates. The Office of Pesticide Program's Health Effects Division (HED) has conducted aggregate human health risk assessments for 1,2,4-triazole and triazole conjugates which was completed on Feb 7, 2006 (D320683). The Tier II drinking water assessment for 1,2,4-triazole was completed in Feb 28, 2006 (D320682). The potential adverse effect of triazole on the ecological environment for the proposed uses was not addressed in this risk assessment.

- Before difenoconazole breaks down to triazole, it forms CGA205375, (1-[2-Chloro-4-(4-chlorophenoxy)-phenyl]-2-[1,2,4]triazol-1-yl-ethanol). CGA205375 has potential to be slightly more mobile in the soil than difenoconazole, based on the registrant-submitted adsorption/desorption study. The potential adverse effect of this degradate on the ecological environment was not addressed in this risk assessment. If this degradate is shown to have potential ecological or human health concern, additional fate and transport studies may be requested at later time.

- No data were available to assess the chronic toxicity of difenoconazole to estuarine/marine fish. The LC_{50}s for estuarine/marine fish were comparable to the LC_{50}s for freshwater fish, suggesting similar acute sensitivity to difenoconazole. In the absence of data, the acute to chronic ratio (ACR) from the freshwater fish data was used to estimate a NOAEC for estuarine/marine fish. The most conservative acute value of 819 µg ai/L was used for estuarine/marine fish. The most sensitive LC50 value for freshwater fish (810 µg ai/L, rainbow trout) and chronic NOAEC value (8.7 µg ai/L, fathead minnow) were used to estimate a fish ACR. An estimated NOAEC value of 8.8 µg ai/L was derived for estuarine/marine fish. Uncertainties with this calculation include species sensitivity and extrapolation error, given that quantified sensitivity factors do not currently exist. The ACR relied on extrapolating from freshwater to estuarine/marine environments and between two freshwater fish species, the rainbow trout and the fathead minnow, which may have different sensitivities to this chemical.

- Chronic estuarine/marine crustacean toxicity was based on a mysid shrimp life cycle toxicity test which resulted in a non-definitive NOAEC < 0.115 µg ai/L for reproductive effects (number offspring/female/reproduction day). There were significant adverse effects on reproductive success at all treatment levels compared to the negative control (42-68%). There is uncertainty associated with the calculated non-definitive RQ values for chronic effects to mysid shrimp which range from >11.22 to > 99.13 for all the proposed uses.